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Food-Drug-Cosmetic Law JOURNAL

1961 Joint National Conference of Food and Drug Administration and The Food Law Institute, Inc.— Papers Presented at FDA Session on November 27

A COMMERCE CLEARING HOUSE PUBLICATION
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The editorial policy of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis, contributions and comments are invited.

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REPORTS

TO THE READER

The 1961 Joint National Conference of the Food and Drug Administration and the Food Law Institute, Inc., was held on November 27 and 28, 1961, in the auditorium of the United States Department of Health, Education and Welfare, Washington, D. C. The Federal Hazardous Substances Labeling Act was discussed in detail during the morning session of November 27 as were the laboratory developments in food and drug regulation.

The following organizations cooperated in this conference: American Medical Association, Association of Food and Drug Officials of the United States, The Food Additives Committee of the Manufacturing Chemists' Association, The Food Protection Committee of the National Research Council, George Washington University Graduate School of Public Law, Grocery Manufacturers of America, Inc., The Nutrition Foundation, Inc., The Packaging Institute, Inc., and the Pharmaceutical Manufacturers Association.

This issue of the FOOD DRUG AND COSMETIC LAW JOURNAL is devoted to the Food and Drug Administration morning session of November 27. The moderator of the opening session was *Mr. George P. Larrick*, United States Commissioner of Food and Drugs. Commissioner Larrick's introductory remarks followed the invocation by *Frederick Brown Harris, D. D.*, Chaplain of the United States Senate, and the welcoming addresses by *John L. Harvey*, Deputy Commissioner of the Food and Drug Administration and *William T. Brady*, Chairman of the Board of Trustees of the Food Law Institute, Inc.

In his discussion of the administrative problems in the regulation of hazardous substances, *John L. Harvey* covers the questions of definition, label placement and designation of type size, and exemptions to the law. He clarifies the areas of coverage and states that the statute is in consumer interest and with the aid of industry, great progress can be made in reducing the death rate due to poisoning from household substances.

William W. Goodrich, Assistant General Counsel for the Food and Drug Division of the FDA, explains the possibilities of litigation arising from the regulations of the Federal Hazardous Substances Labeling Act. He agrees that the law itself is new, but says that many of the provisions of the law were drawn from the Food, Drug and Cosmetic Act and have been enforced for 20 years.

Scientific considerations of the Federal Hazardous Substances Labeling Act is such an extensive topic that it was covered in two papers. In the first, by *Dr. E. William Ligon, Jr.*, a pharmacologist in the Division of Pharmacology of the FDA, the author limits

his remarks to four of the seven properties which make a substance hazardous. These four are the substances which are toxic, irritant, corrosive and strong sensitizers. His discussion outlines the collection and application of biological data to these areas. The second of the papers on this subject is by *Dr. Daniel Banes,* who is the assistant director of the Bureau of Biological and Physical Sciences of the FDA. His paper covers the other three of the seven properties which make a substance come under the heading "hazardous" — flammable, pressure-generating and radioactive. The latter group demands physical and chemical data rather than biological data to provide a uniform and practical basis for classification as hazardous.

The second major discussion topic during the morning session of the conference on November 27 was the laboratory developments in food and drug regulation.

Dr. Henry Fischbach, the director of the Division of Food of the FDA, discusses the organization and the operation of that division. He includes the problems of investigation of food composition, of pesticides and of food packaging materials and describes some of the methodology that is applied to this research.

The question of drug chemistry was reviewed by *Dr. Frank H. Wiley,* director of the Division of Pharmaceutical Chemistry. He explains the new procedures that have been developed for the analysis of drugs and the application of these tools to the examinations of chemical and physical properties of substances analyzed by his division.

In a very interesting report from the Division of Pharmacology, *James R. Cribbett,* assistant to the director of that division, reviews the work done in the measuring of food contamination as a result of radioactive fallout. He discusses several investigations and test series which have been made to determine the harm to the human body resulting from the consumption of foods containing radioactivity.

The paper presented by *Dr. Glenn G. Slocum,* the director of the Division of Microbiology of the FDA, contains a report of the incidence of food-borne disease. He explains that microscopy serves as an important tool for measuring many forms of decomposition, contamination and insanitation in both food products and establishments. He states that emphasis upon bacteriological control of food production by industry and regulatory officials should be most effective in reducing the risk of food-borne disease.

At the Food Law Institute dinner the evening of November 27, *Dr. George Y. Harvey* addressed the participants in the conference. Dr. Harvey is the chairman of the Second Citizens Advisory Committee. He told the audience about the work done in 1955 by the First Citizens Advisory Committee and how his committee plans to work to keep both industry and the general public fully informed of the law and operations under it. The responsibilities of the FDA and of industry are outlined, but in addition to their responsibilities, Dr. Harvey feels that the safety of the public cannot be assured unless the public is well educated in order to protect themselves.

The next issue of the FOOD DRUG COSMETIC LAW JOURNAL will contain papers from the industry and the consumer sessions of the FDA-FLI conference as well as the panel discussion which brought the conference to a close.

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Food·Drug·Cosmetic Law
Journal

Welcoming Address

By JOHN L. HARVEY

Mr. Harvey, Deputy Commissioner, Food and Drug Administration, Department of Health, Education and Welfare Opened the Food and Drug Administration-Food Law Institute Conference in Washington, D. C. on November 27, 1961, with This Address.

IT GIVES ME GREAT PLEASURE to add the sincere welcome of the Food and Drug Administration to that of Mr. Jones as we open this Fifth Food and Drug Administration—Food Law Institute Conference.

You will be interested and possibly some of you will be surprised to know how much we have come to value these annual meetings. In addition to furnishing a needed avenue for free exchange of information between consumers, industry and government, these conferences offer a unique opportunity for key representatives of each group to exchange ideas informally, and to recognize and resolve little problems before they become big.

Of necessity, much of the ordinary exchange of information between government, industry and consumers takes place below the top management level. There just aren't enough top managers to do all of the conferring that is required in today's society. This means that top managers in the Food and Drug Administration must rely heavily upon others in the organization for information upon which to form opinions about top management in industry and, likewise, top management in industry must rely upon second-hand information much of the time to form its views about government. It is human nature for a man to regard his job as the most important or at least one of the most important jobs performed for his company, or his department. If he didn't, we would not want him on the payroll. But because he

takes his job so seriously, it is quite possible for him to place an inordinate amount of importance upon any obstacles that may fall in the way of the accomplishment of his objectives. So we may receive a report in all sincerity, after some of your representatives have been in to talk with us about a food and drug problem, that "X" company is certainly hard to get along with. Perhaps you upon occasion receive reports from your employees about difficulties they have encountered in reaching a meeting of the minds in the Food and Drug Administration.

For this reason, if no other, it is most important that the top leaders of the Food and Drug Administration and of industry and of consumer organizations sit down together periodically to talk with each other face to face and to determine for themselves what kinds of individuals they are dealing with. For our part, we have been gratified to find that the key industry leaders who attend these conferences and talk with us during and after, are, in fact, just people, and in most cases quite reasonable people at that. And I know that some of you have been surprised in past years after talking with us to find that we are just people, too, and a bit more reasonable than you might have thought.

In view of the heavy legislative program that the Food and Drug Administration has had for the past few years and the likelihood of a heavy legislative program to continue, it is important that we know each other and that we feel free, top management and top legal counsel of our various organizations and agencies, to exchange ideas informally and search for points of view that give good consumer protection and are not destructive of either government or industry. We are satisfied that this has been possible to a greater extent in recent years than before and that the result has been due to a significant degree to the background being laid at annual conferences such as this one.

But we don't want to stop with better communications between top managements. We need better communications and better understanding all up and down the line to aid in law compliance and to allay unfounded fears and suspicions. To meet this need, we have strengthened our Division of Public Information so that it is able to supply helpful facts in response to consumer inquiries and to supply greater informational service to the trade. We have expanded the consumer consultant program which was described at last year's conference. Among other things, our consultants have held a series of FDA-consumer conferences in 16 of our district offices. We have formed a Public Service Advisory Committee comprised of representatives from major consumer organizations of the nation. We have

cosponsored with the American Medical Association a National Congress on Medical Quackery which should lead to more effective regulation of quack drugs, fake devices and worthless or misrepresented nutritional supplements.

Lest there be some misunderstanding, I would like to point out that we are not planning to substitute education for regulation where legal actions are necessary. We think education and better communications can result in greater law compliance but our experience indicates clearly that there are some situations which cannot be corrected soon enough or adequately enough without resort to the formal sanctions of the law. We will still seize bad lots of merchandise. We will still seek injunctions to restrain continuing serious violations. We will still bring criminal actions where the nature of the crime appears to demand them. But we are going to make a sincere effort to make it possible for every regulated firm to have a clear understanding of what the law requires and have a clear guide to the steps he may take to meet the requirements of that law fully and without incurring the threat of formal legal actions.

We welcome each and everyone of you and trust that you will find these two days of meetings to be most worthwhile. **[The End]**

SENTENCE FOR BOOTLEGGING DRUGS

A doctor of medicine from Bangor, Maine, and a service station night manager from Lordsburg, New Mexico, pleaded guilty and have been given heavy sentences in two separate federal court actions for "bootlegging" amphetamine pills.

Dr. George H. Horton was charged with selling large quantities of sodium pentobarbital capsules and amphetamine sulfate tablets outside of his legitimate practice. Judge Edward T. Gigoux, United States District Court, Portland, Maine, sentenced Horton to a $5,000 fine and a six-month term in jail. The jail term was suspended and he was placed on a two-year probation.

The Food and Drug Administration investigated Dr. Horton's activities after receiving complaints from doctors and a hospital that he was selling amphetamines by mail to patients who were under the care of other physicians. Dr. Horton repeatedly dispensed the pills in peanut butter and coffee jars without giving physical examinations to FDA inspectors who posed as patients. He sold the pills in large quantities even after the "patients" told him that they were not using them for medical purposes but were reselling them.

In the other case, José Adalberto Munoz was charged with selling amphetamine sulfate tablets to Food and Drug Administration inspectors posing as truck drivers.

The Federal Hazardous Substances Labeling Act

By JOHN L. HARVEY

Mr. Harvey, Deputy Commissioner of FDA Presented This Address Before the 1961 Joint National Conference of the FDA-FLI.

AT THIS CONFERENCE last year Assistant Commissioner Winton Rankin presented a brief look at the Federal Hazardous Substances Labeling Act. He described some of its provisions, some of its background and predicted that implementing regulations would be issued shortly for the joint guidance of government and industry. It would seem appropriate to bring you today a progress report under this important statute.

The law provided for an effective date of February 1, 1961, unless prior to that time a finding could be made that conditions existed which necessitated the prescribing of additional periods of time for compliance, up to a total of 18 months or until February 1, 1962. As the February 1, 1961, date neared it became obvious that much remained to be done. We therefore extended until August 1, 1961, the application of the sanctions of the statute except as applied to extremely flammable and flammable substances (other than solids and those in pressurized containers) and to substances which were highly toxic. The statute itself prescribed specific tests to be applied to determine whether a product met any of these three definitions, and therefore there should have been no doubt on the part of any manufacturer whether his product did or did not so classify. The other kinds of hazardous substances, irritants, corrosives, strong sensitizers, flammable solids and contents of self-pressurized containers and those which generated pressure were not precisely defined in the statute and needed definition by regulation.

The next significant development was the publication of proposed definitive and interpretive regulations on April 29, 1961. We had no delusions that our proposed regulations would receive no comment,

but we were not prepared for the deluge of comments we did receive. Surprisingly, many quite critical comments were apparently based on the assumption that these regulations were not really proposals but were a prepublication of what would be finally issued as the rules under which everyone must play. Few proposed regulations have elicited so much of this kind of response as did these. Many thoughtful and very helpful suggestions were received. Pleas were made by many that they wished an opportunity to be further heard. Some demanded a public hearing, which was not authorized by the statute. A meeting was therefore held on July 13 and 14 in this auditorium at which time many firms, associations and organizations presented their views on this subject.

All of these comments were studied, discussed and evaluated. Many of the suggestions made in response to the proposals were accepted, some others we accepted in part and some were rejected completely. For some of the scientific problems posed we empaneled two committees of outstanding scientists to assist us. One of these was composed of outstanding experts in the field of dermal toxicity. The other consisted of outstanding national and international experts in the fields of pharmacology and clinical toxicology. The final regulations were published in the *Federal Register* on Aug. 12, 1961.

A few of the regulations are worthy of discussion. One is the definition of "containers intended or suitable for household use." This section in the proposed regulations was criticized from three standpoints.

One was that the inclusion of the concept of labeling at the time of purchase was uncalled for by legislative history and was an unwarranted extension by us. Secondly, that the proposal placed in jeopardy the manufacturer whose product might reach a home by being stolen from an industrial plant and thirdly, the definition would include such things as janitorial supplies in an apartment house.

The final regulation does not make any change in the concept that warning should be present at the time of purchase. Our position is not that the purchaser necessarily needs to be protected in the grocery or hardware store, but that purchase naturally flows as part of the conditions of use. We believe that the purchaser should at the earliest possible time and in the plainest possible way be made aware of any inherent hazards of the product which she is purchasing so that she might take it home and store it with the full knowledge of these hazards. Language was added to take care of inadvertent household use of products not intended or marketed for such use.

An article labeled and marketed solely for industrial use does not become subject to the act because an industrial worker may misappropriate supplies for his own use. No change that would allow janitorial supplies to be exempt from warning labeling was made. Apartment houses, even those allowing adult occupancy only, are not immune from lively and curious children.

Statute Definition of Highly Toxic

The statute defines highly toxic by ingestion as a product which will produce death in half or more than half of the group of laboratory white rats when fed with a single dose of the substance at a rate of 50 mg. per kilo of body weight. They did not provide similar guidelines for a product which would be "toxic" but not "highly toxic."

Our scientists advised us that for the adequate protection of public health the definition of toxic by ingestion should cover those products which would produce death in half of the animals tested in a single dosage up to 5 gm. per kilo of body weight. The regulations proposed this level and we found it to be a very controversial point. It was stated by many that the 5 gm. per kilo rule would bring under this statute 75 per cent of the products now used in the household. A general cry of "over-labeling" which would defeat the protective purpose of the statute was heard. We again asked the advice of our panel of scientists and pointed out to them the arguments put forth to reduce this definition to a one or two gm. per kilo rule. They advised us to retain the 5 gm. per kilo point for the definition of toxic, insisting that to do otherwise would eliminate from coverage many products that were actually hazardous. They further advised us that there were a substantial number of products in the LD_{50} dosage range between 500 mg. and 5 gm. that presented no practical hazards. They recommended that we seriously consider exempting such products from the required labeling. I will discuss for a few minutes our plans in this regard.

Our proposal possibly did not make entirely plain the fact that human experience on the final product was actually the test, whether such experience showed a greater or lesser hazard than would be indicated by any statutory or empirical test applied. We quite willingly adjusted the language of Section 191.2 to indicate this view.

The best and practically the only source of information as to poisoning incidents that were occurring was the National Clearing House for Poison Control Centers and the individual centers them-

selves. Our original survey of these, disclosed a group of substances which were responsible for most of the poisoning incidents due to products which would be controlled by this statute. These products were carbon tetrachloride, diethylene glycol, ethylene glycol, kerosene, methyl alcohol and turpentine. It was therefore proposed to call these substances and mixtures containing them as "highly toxic" substances and to require the strongest kind of warning labeling for them. To this proposal we received voluminous comment to the effect that the designation "highly toxic" denoted a dose weight relationship which did not exist for the named substances. We placed this question before our panel of experts who besides being scientific experts were well acquainted with the practical problems involved in poisoning incidents. They agreed that the term "highly toxic" did denote a dose/weight relationship and that none of the named substances qualified as highly toxic under this rule. They advised, however, that each of these substances did have special hazards which required special labeling for the protection of the public health and safety. They recommended specific labeling and specified the percentage limits of each of the products they felt required such warning labeling. These suggestions resulted in substantial changes in Section 191.7.

Label Placement

The regulations dealing with label placement and the designation of type size for some of the warning statements elicited much comment from industry, from consumers and from consumer groups. Our original proposals specified that all of the required warning labeling be on the main panel and in a size of type that would leave little doubt that anyone handling the product would see it. We were told that there was absolutely no authority in the act to designate the placement of the warning labeling that should appear but that manufacturers could be guided by the requirement "prominent" and "conspicuous." We were told that the proper place for all warning statements was on the panel including the directions for use on the basis that it was at this point immediately before the product was to be put into actual use that the user needed the protective information. We were persuaded that many of the arguments on product and trademark identification and product appeal had validity. We were not persuaded that warning labeling should not be conspicuous at the time of purchase. This matter was resolved, and we believe reasonably, by requiring on the main panel the signal word, a statement of the principal hazard or hazards and directions for reading carefully the

other warning labeling located elsewhere on the label. The remaining label requirements grouped together with the exception of the name of the manufacturer, packer, distributor or seller, may appear elsewhere. Our type size requirements were reduced. Minimum sizes are specified but in general requirements are that the type size shall bear a reasonable relationship to the other printing on the label.

The last matter dealing with the regulations that I would like to discuss deals with the methods specified for determining whether a product is hazardous because it is toxic, an irritant or corrosive. Considerable comment was received on this subject on the basis that we should not specify the particular method that would have to be used. The commenting scientists in particular desired professional leeway. Administratively we found ourselves unable to yield to this request. We have no objections whatever to anyone using any method they desire to arrive at their opinion as to whether a product is a hazardous substance under this statute. We did feel compelled to go on record with the method that the government would use on their products to make such a determination. We desired to prescribe a precise and reproducible method against which we or anyone can test products and determine if they meet the definitions. Latitude on methods would only be confusing. To leave the method to be used unspecified, would mean that every lawsuit under this statute would include complex issues validating or invalidating testing methods. The methods proposed in the final regulations may be subject to improvement both as to precision and reproducibility. We have asked industry to help us in making these methods better if such can be done.

Exemptions

The act provides for the Commissioner of Food and Drugs the authority to exempt hazardous substances in containers intended or suitable for household use from the complete warning labeling as specified in the law if, because of size of the package, the minor hazard involved or for other good and sufficient reasons he can conclude that the protection of the public health and safety does not require all of the labeling. This provision is the way that those substances which have a LD_{50} of less than 5 gm/kilo but from a practical standpoint are not hazardous may be exempted from all or part of the labeling.

We have been asked whether this is the only way that a product with a LD_{50} of less than 5 gm/kilo can be legally exempted from the warning labeling. The Federal Hazardous Substances Labeling Act

is not a licensing or registration statute. Therefore, there is no compulsion for manufacturers to list a product with the Food and Drug Administration or to find out what the FDA thinks about it before deciding on labeling. The law places this responsibility on industry. If, however, a manufacturer has a product which he concludes under the terms of the statute will not cause substantial personal injury or substantial illness during or as a result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children, he does not need to place the labeling required by the statute on his product. He must, however, be prepared to defend his decision should we take a different view.

On the other hand, there are two other possible avenues he may follow. First, he may come to the offices of the Food and Drug Administration with complete formula and processing information and seek our advice. If sufficient information is furnished we may be able to advise him whether his product is amenable to the statute. Such advice is strictly informal but would give some assurance to interested individuals of how we view his products. The second route would be to petition for a formal exemption, if the product meets the technical definitions for a hazardous substance.

The Federal Hazardous Substances Labeling Act does not include petitioning machinery such as the Pesticide and Food Additive Amendments to the Food, Drug, and Cosmetic Act. We have, however, established informal machinery to serve this purpose. We ask that firms who have products which they feel do not present hazards but do meet the definition for a hazardous substance, to furnish for such products complete quantitative formulas, complete labeling now applied and that intended to be applied if exemption is granted, complete toxic reports of tests on animals either on finished products or individual ingredients, the results of tests for irritancy, corrosiveness, or flammability in the regulations if appropriate, and physical data which might be important. Very definitely we are asking that as much data as possible be submitted showing that in the laboratory of human experience the product or products do not cause harm. As a result we have already received petitions from some 18 firms or associations. We have found it necessary to reject one petition on the basis that we could not conclude either that the hazard was minor or that the size of package precluded the chance of accident. Several others are being favorably considered and we would expect to publish in the *Federal Register* in the not too distant future some

further exemptions of partial or complete warning labeling. There will be no publication of those whose petitions are denied. We hope, in those petitions that are granted, to issue exemptions on the broadest possible basis rather than on individual products where the facts warrant. The act is scheduled to go into full effect on February 1, 1962. Congressman Kilgore, as you undoubtedly know, introduced a bill, just before the adjournment of Congress, designed to further extend the discretionary powers of the Commissioner to place in abeyance provisions of the statute as they apply to specific kinds of hazardous substances and packages thereof. The Department of Health, Education and Welfare has not as yet taken a position on this legislation. I would not like to predict at this time its outcome. I would strongly recommend that all manufacturers of products which come under this statute initiate or proceed with their label revision to bring their products into compliance. It would be inconsistent for us, even if the extension legislation is passed, to grant the same further extension to products whose labels have not been revised at all as those which bear some warning labeling within the spirit if not the letter of the law and its regulations.

Labeling laws and changes in labeling laws are not new to the Food and Drug Administration. We have never followed a policy of initiating a vigorous sampling and enforcement campaign against technical violations of any new rules. We see no reason why this policy should be abandoned in the case of the February, 1962, effective date of the Federal Hazardous Substances Labeling Act. We will, however, formulate an enforcement campaign designed to carry out the provisions of the statute which will of course take into consideration not only the degree of hazard the product presents but the warning labeling it might already have.

This statute is very definitely one in the consumer interest. It was brought about because of an alarming increase in poisoning incidents or the result of better reporting of them. We hope that through the cooperation of industries we can make some progress in reducing sufficiently the deaths due to poisonings from household substances.

We hope that next year we can report substantial gains in this area. **[The End]**

Legal Problems Arising Under the Federal Hazardous Substances Labeling Act

By WILLIAM W. GOODRICH

The Author Is the Assistant General Counsel for Food and Drugs in the United States Department of Health, Education and Welfare.

IT IS INDEED A CHALLENGING ASSIGNMENT to discuss, in about 20 minutes, the legal problems that arise out of the Federal Hazardous Substances Labeling Act.

In a sense it should be quite an easy job. This is a new law. It has not yet been before any court for interpretation. My opinions, therefore, may be expressed without the inhibitions of any court opinions that may not agree with me.

But many of the provisions of this new law are not really new at all. They were drawn directly from the Federal Food, Drug, and Cosmetic Act, with which we have lived rather closely over more than 20 years. Judicial guidance to the meaning of the law is readily available in a great many reported decisions. And the administrative procedures Congress has provided are to be fitted into the over-all scheme of the Administrative Procedure Act which is now about 15 years old.

When we reviewed the extensive legal arguments filed with the comments on our proposed regulations, we were given to understand that many—if not most—of our proposals were plainly illegal or beyond our authority.

Nonetheless, the regulations have been finalized. Arguments over their validity will have to await the effective date of the enforce-

ment provisions, and any legal actions we may bring on the basis of the legal views which underlie the regulations.

We think it is rather clear that *all* of the regulations are not illegal. For example, there were many complaints about our regulation prescribing when the required cautionary information must be on accompanying labeling. This regulation says that all written, printed and graphic matter which accompanies the hazardous substance in its distributional pattern, and which has any directions for use, is labeling which must bear the information required by the law. This concept is not new at all. It is an adaptation of three Supreme Court opinions in cases decided in 1948 under the Federal Food, Drug, and Cosmetic Act.

Front Panel Label Placement

And perhaps the most controversial of all the regulations—the requirement of front panel placement—is certainly not completely without judicial support. Indeed, a very old Supreme Court case under the Food and Drugs Act of 1906, the *Antikamnia Chemical Company* decision in 1914, upheld the validity of a comparable interpretive regulation, when it was concluded that, because the regulation "fulfilled the purpose of the law," it was not an attempt by administrative action to add an entirely new requirement.

More recently, the Court of Appeals for the Second Circuit upheld administrative regulations retroactively revoking certificates of harmlessness for coal-tar colors. These regulations, too, were attacked on the ground that the law did not authorize them. Citing the *Antikamnia* decision, the Court of Appeals held that the power to revoke the certificates was necessarily implied from the power to issue them.

Applying these principles here, the law requires that the warning information be located "prominently" and "in conspicuous and legible type in contrast by typography, layout or color" with other label information. We firmly believe that the front placement regulation fulfills the purpose of this law—that it is a reasonable interpretation of what is required for compliance—and that it can be enforced.

We think that it is proper to start with the assumption that most, if not all of the regulations, will receive judicial support. And, if they will, it seems prudent to plan for compliance with the requirements of the regulations, as well as the less explicit requirements of the law itself, in mind. We have, of course, made it clear that the regulations

were not written by a "moving finger of fire," and that they can and will be modified when sufficient reasons are advanced. Until they are, however, they represent our best judgment of what the law requires and how the requirements may be fulfilled.

There is in this new law, in addition to the authority for the initial interpretive and procedural regulations, authority to make it specifically applicable to certain products, to prescribe special labeling for special hazards, to name the strong sensitizers and to prescribe tests for flammable solids and the contents of self-pressurized containers.

The only significant legal point that needs to be made before so large an audience is that but one class of these important regulations is bound up with special hearing procedures and judicial review. Whenever the Secretary, to avoid or resolve uncertainty, proposes to make a specific substance subject to the labeling requirements of this act, he must proceed by formal rule-making procedures comparable to the food additive procedures. But in requiring special hazard labeling, in granting exemptions for small packages and minor hazards and indeed in all other important respects, the department is not subject to the procedures for formal rule making. Any judicial review in these areas will have to come, we believe, in the enforcement actions—in seizure, injunction, or criminal actions brought against misbranded packages or against persons responsible for doing or causing any of the prohibited acts with respect to misbranded packages of hazardous household substances.

The legal problem foremost in the minds of many is how this law, which becomes fully effective on February 1, will apply to substances prepared, packaged, shipped, or held for sale before the effective date.

Congress has said that no penalty or condemnation shall be enforced for any violation of this act which occurs before its effective date. This, of course, precludes prosecution or seizure based on the current shipments of most misbranded packages. But there is no reason why articles which are misbranded and are held for sale after shipment in interstate commerce cannot be proceeded against, at least by seizure and condemnation, once the effective date has passed. And an article is in the "held for sale" status, through all of its intrastate sales until it reaches the ultimate consumer. Even if the article were condemned, it would not necessarily have to be destroyed, because the law allows it to be relabeled to be brought into compliance.

Mr. Harvey has discussed the problem of proposed extension legislation, as well as the probable administrative attitude on enforcement after the effective date. There is no need for me to comment beyond the point that the law gives the department adequate discretion to plan and execute a sound enforcement program, without wasting its efforts on the less significant or even the less compelling violations.

At the same time, it should be said that this law extends its protection to substances which are repacked from bulk containers into smaller containers for sale to the householder. In this sense, it is important to the local retailer, as well as to the manufacturer and interstate distributor. The kerosene we buy for our fire lighters and the gasoline for the power mowers will be in misbranded packages if the appropriate warnings are not provided by a stick-on or other suitable label. It is prudent to plan now—if you have not already planned—for the earliest possible compliance. The high purpose of the law requires it, aside from any question of extension dates and discretion in enforcement.

Factory Inspections

One final legal point is worthy of mention. It is what authority the Food and Drug Administration has to make factory and other establishment inspections.

The statute follows the 1952 amendment to the Federal Food, Drug, and Cosmetic Act. But its legislative history is not burdened with questions and doubts that arose in 1952. It is reasonably clear, from this history and this language, that the inspectors are entitled to enter and to inspect to all reasonable extent in light of the purpose of the statute to determine whether hazardous household substances are being prepared and properly labeled for interstate distribution and for sale after shipment in interstate commerce. The inspection is not confined to the finished articles as packaged for sale or other distribution, nor, we believe, to manufacturers who have decided that their products are subject to the new labeling requirements.

Factory inspection is new to many firms subject to this new law. But it is the only really feasible method of enforcement. It is a planned operation of routine surveillance. It is not a quasi-criminal proceeding such as a search warrant. And it has educational and preventive effects, as well as enforcement values.

We have heard arguments that firms who decide for themselves that their products are not subject to the law may refuse to admit the inspector and to provide him the requested opportunity for inspection. The validity of such a position will have to be litigated, if it is maintained. We are determined to exercise all reasonable efforts to effect full and reasonable compliance with the labeling requirements. We do not accept the idea that the manufacturer's say-so that his articles are not covered by the law forecloses inspection.

Indeed, we think it is pretty well established that inspections to determine whether articles are subject to the law is a part of our proper concern. Investigations to determine whether persons are subject to a regulatory law are as much authorized as are investigations to determine whether the law has been violated. The Supreme Court has made it clear, we think, that an administrative agency "may take steps to inform itself as to whether there is a probable violation of the law." It is not necessary that the agency be prepared to charge a violation of the law before it can exercise a delegated investigative function. Any such interpretation would defeat a major purpose of the law to prevent foreseeable accidents.

Long experience with factory inspection has convinced us that it can be, and is, fairly exercised without unduly interfering with the manufacturer's business. His trade secrets are protected by the criminal provisions of this statute. And inspection is the very keystone to compliance and preventive enforcement in the public interest. We hope we will have cooperation from the affected—and possibly affected —industry as we proceed to the administration of the new law.

We are sure there are many other legal problems that concern some or many in this audience. We will answer questions on tomorrow's panel, but we want it known the Food and Drug Administration stands ready at all times to assist in working out any problem that this law may create for any of you. **[The End]**

WORLD HEALTH ORGANIZATION REPORT

The World Health Organization has issued a timely report on advertising in the drug industry. "Pharmaceutical Advertising" presents a survey of existing legislation in 22 countries, including the United States, which aims to control pharmaceutical advertising. It discusses both advertising to the public and technical advertising, or advertising intended for the medical profession. The report is reprinted from the WHO *International Digest of Health Legislation*.

Scientific Aspects of the New Act

By DR. E. WILLIAM LIGON, JR.

The Author Is a Pharmacologist in the Division of Pharmacology, Bureau of Biological and Physical Sciences of the FDA. In His Address, E. William Ligon, Jr. Outlines Some of the Considerations Involved in Collecting and Applying Biological Data in the Areas Covered by the Act.

DR. BANES HAS LISTED for you seven different properties of substances which may render these hazardous. If these are in containers intended or suitable for household use and are capable of producing injury under any customary or reasonably foreseeable use, including reasonably foreseeable ingestion by children, they will require appropriate labeling under the Federal Hazardous Substances Labeling Act.

I shall limit my remarks to four of these—toxic, irritant, corrosive and strong sensitizer. I shall outline some of the considerations involved in collecting and applying biological data to these areas.

Before discussing these, however, I would like to remind you that the area before us covers an almost fantastically complex and varied array of products. Based upon our review of factory inspection reports and formulation information submitted voluntarily by manufacturers seeking our advice, the Division of Pharmacology estimates that there are between 250,000 and 600,000 products in the field. About one-third of these clearly lie outside the act, and a somewhat smaller number appear to lie well within the scope of the act. It is with the rather large intermediate group that our greatest problems lie.

Determination of Toxicity

Let us look at some of the problems associated with a determination of whether a product is "toxic." The statutory definition is distinctive but not precise. Any attempt to define the break-point

in terms of a specific quantitative value inevitably brings problems. Regardless of the level of toxicity which is chosen, there will be some products which do not fit the pattern. There will be some which are positive or within the critical value, and yet which do not require all of the elements of precautionary labeling specified in Section 2(p)(1) of the act. There will be other products which are outside the critical value, and yet which either have special hazardous properties not recognized by the definitions, or which have properties which make them unusually likely to be misused or used without reasonable care. Thus in applying the 5-gram rule for evaluating toxicity by ingestion we expect to be able to exempt many such substances as neutral soaps; light, fluffy, essentially neutral washing powders; and certain thick, viscous adhesives. On the other hand when kerosene and related petroleum hydrocarbons, most of which are not toxic within the 5-gram rule, are taken in by mouth they often produce gagging or vomiting, and the chemical may enter the trachea. Severe chemical pneumonitis may result and because of this special property and a high incidence of adverse human reaction we have listed kerosene and products containing it in paragraph 191.7 and have prescribed special labeling. We would anticipate that a number of kerosene containing products can be shown not to produce this effect—either because they are thick, viscous mixtures and cannot be aspirated or because the hydrocarbon is so bound or emulsified that it will not spread over the lining of the lung even if aspirated. Methyl alcohol and glycol antifreezes do not fall within the 5-gram rule by animal data, but because of the strong tendency for some people to drink any alcohol, including methanol, and to think of all antifreezes as "alcohol," we found it necessary to list these also in paragraph 191.7 and prescribe special labeling.

Toxic by ingestion, as described above, is pegged on a 100-fold factor as compared to the statutory definition of "highly toxic," but with substances toxic and potentially hazardous by absorption through the skin we felt we could cover most of the practical hazards by application of a factor of ten, since most household aids can be more readily removed from the skin as compared to removal from the stomach. Even here, however, when special hazards are recognized—as the special ability which benzene has of producing abnormality in blood forming tissues—we will need to require statements warning against skin contact even for products whose lethal dose is above two grams per kilogram.

Toxic by Inhalation

With products toxic by inhalation, we have again used a factor of 100, and we believe this will work no hardship on the industry. It is quite obviously necessary to consider as hazardous any volatile solvent which readily attains a concentration in air which would be lethal on relatively short exposure, and a factor of 100 is necessary in order to cover most of these. We recognize that for many or even most substances an air concentration of 200 milligrams per liter is unattainable, and we remind you that testing need extend only to those air concentrations which can be anticipated under customary or reasonably foreseeable use. Fortunately, industry has a great deal of information on the volatile solvents, both from the laboratory and industrial health standpoints. Information on irritancy, corrosiveness and sensitization, however, is much less readily available.

We have defined "irritant" on a two-fold basis—human experience and laboratory data. The laboratory test on rabbits is one which has been repeated thousands of times by our staff, and the empirical score of five was chosen to serve as a basis for requiring the signal word "irritant" only in the labeling of those substances with a substantial probability of producing injury if left in contact with the skin. The test for irritant to the eye is intended to require warnings about eye contact only on those substances which can be expected to produce relatively severe or permanent injury if left in the eye for an appreciable period of time.

Corrosive

We have defined corrosive on the basis of human experience or as lying beyond the scale on the rabbit skin irritancy test. By listing in paragraph 191.109 we have extended, for the time being at least, the definition of corrosive as implied in the Caustic Poisons Act, for those substances named therein. This was done with the full understanding that a number of these substances will be found to be corrosive at lesser concentrations than those listed, and will therefore require labeling at these lower concentrations.

We have not attempted an empirical definition of sensitizer at this time, but will expect to list additional substances in paragraph 191.6 as the information comes to our attention.

This act places upon the manufacturer a statutory requirement that he know the nature of his products and their hazards, but does

not require that he bring his information to us. Since the burden of proof that a specific product is in violation appears to rest with us, it is essential that we gather a tremendous mass of information in this field. In addition, many consumers, or consumer groups, and many merchandisers, including a fairly large number of manufacturers, come to us for opinions as to the adequacy of labeling for their products.

I believe most of the necessary information on toxic properties and hazards of volatile solvents is available in the files of the basic manufacturers, and much of it has been published. Much of the needed data on a large number of chemicals is likewise available in the files of basic manufacturers, but little has been published. I suspect that relatively little is known about formulations and mixtures in many areas. It has been particularly distressing to find so little known about dyes and coloring materials in general. It is likewise disconcerting to examine specifications of petrochemicals and find so many are described primarily as to performance with little or no attention to toxicological data.

I close with this general comment. The problems are complex. Many data are available, and many more must be gathered. Each bit of data voluntarily supplied to us will reduce our task, and will hasten the possibility of building a pattern of labeling which will fulfill the requirements of the Federal Hazardous Substances Labeling Act for the protection of the consumer. **[The End]**

FDA ENFORCEMENT PROBLEMS EMPHASIZED

Lack of funds, personnel, facilities and equipment necessary for the Food and Drug Administration to carry out its enforcement activities properly has been emphasized by Mr. K. L. Milstead, Deputy Director of the Bureau of Enforcement in a speech presented at the Second Annual Attorney General's Consumer Protective Conference at Detroit, Michigan, on November 2, 1961. Widespread quackery in the marketing of drugs, devices, nutritional products and cosmetics, for instance, is not being halted by the law largely because enforcement is difficult, expensive and time consuming, although more emphasis on informational and educational programs may help, he said.

Short weight shipments of food products found by a recent FDA survey is attributed by the FDA to its inability to devote the necessary time to enforcement in recent years. Other areas which have lacked adequate enforcement because of physical inability are inconspicuous labeling violations and deceptive and misleading packaging. FOOD DRUG COSMETIC LAW REPORTS.—¶ 7683

The Federal Hazardous Substances Labeling Act: Scientific Considerations

By DR. DANIEL BANES

Dr. Banes Is the Assistant Director of the Bureau of Biological and Physical Sciences of the Food and Drug Administration. In His Address He Explains That the Effective Execution of the Law Depends Ultimately Upon Scientific Criteria.

EVERY DISCUSSION OF THE LAWS enforced by the Food and Drug Administration must eventually deal with scientific considerations. The Food and Drug Administration always has been unique among law-enforcement agencies for its thoroughgoing reliance upon scientific criteria in judging whether a given article, by its properties and actions, violates the provisions of the law. The effective execution of the Federal Hazardous Substances Labeling Act, like that of the older laws which we administer, depends ultimately upon objective scientific criteria.

The act enumerates seven different categories of hazardous substances: (1) articles which are toxic through ingestion, inhalation, or absorption through any body surface, (2) corrosives, (3) irritants, (4) strong sensitizers, (5) articles which are flammable, (6) substances which generate pressure and (7) radioactive substances. However, these terms, although distinctive, are not scientifically precise, and it is necessary to define them concretely, on the basis of empirical data. For instance, what is the exact meaning of "toxic"? Any substance may be toxic under some conditions—even oxygen or water or salt. The law itself describes tests with laboratory animals to determine what substances should be considered highly toxic. But when is a substance "nontoxic," and therefore exempt from the requirements of the law?

In order to evolve a clear definition for "toxic" which is discriminating enough to serve as a meaningful basis for law enforcement, we must accumulate a mass of indicative pharmacological and clinical data. Animal testing and a study of the incidence of adverse reactions in human beings are similarly the touchstones for determining when a substance is corrosive, or is irritant, or is a strong sensitizer. Consequently, our Division of Pharmacology and our Bureau of Medicine have been assigned the responsibility for developing and coordinating our research efforts in this area.

Definitions for the other three categories of hazardous substances —flammable, pressure-generating and radioactive—depend upon physical and chemical data, rather than biological data, to provide a uniform and practical basis for classifying a substance as hazardous.

Radioactive Substances

Radioactive substances include any materials which emit ionizing radiation or particulate matter through nuclear decomposition. However, all radioactive source material and related substances which fall under the jurisdiction of the Atomic Energy Commission are excluded from the purview of the Hazardous Substances Labeling Act. Since practically all of the radioactive materials now produced in this country are subject to the regulations of the AEC, and there is a general public awareness of the dangers inherent in radioactivity, we anticipate that there will be very few radioactive articles offered in the market for household use.

Among the substances which may cause personal injury because they generate pressure are the group of articles known as "aerosol dispensers" or "self-pressurized containers." The used container holding the residual propellant would explode if consigned to the incinerator—a handling or use which could be considered reasonably foreseeable. The definitions and tests in the regulations issued pursuant to the act were intended to identify as hazardous substances such self-pressurized containers, as well as products which evolve gases when heated slightly and subsequently blow out their stoppers, or erupt from their containers, or explode. Hypochlorite bleaches have been notable offenders of this type. Unstable materials which may explode readily, such as blasting agents containing ammonium nitrate as a constituent, or firecrackers, which do explode when ignited at a low temperature, also may be classified as "pressure-generating hazardous substances."

In considering the tests devised to differentiate between highly flammable, flammable and non-flammable substances, we are faced with a striking contrast when we compare the treatment of liquids and solids. The law itself specifies the test, apparatus and analytical criteria which characterize highly flammable and flammable liquids. In brief, the method determines the temperature at which the heated liquid catches fire when exposed to a small flame. If the temperature of the flash point is at or below 80° F, the liquid is flammable; if it is at or below 20° F, the liquid is highly flammable.

These directions for testing liquids are lucid; the test can be applied uniformly to all substances in the liquid state; and the results are clear-cut and reproducible.

Testing Solids for Flammability

With respect to solids, the law states that flammability shall be determined by methods found by the Secretary to be generally applicable to such substances. Since solid substances for household use may exist in a variety of shapes and forms, ranging from the fine granules in a cleaning powder to the vast expanse of a mammoth plastic swimming pool and beyond, it was widely predicted that the Secretary might find it difficult to devise a single method applicable to all of them. This prediction proved accurate. The tests described in the regulations specify a different preliminary treatment for the various forms of solids. Granules and pastes are packed into a metal boat for testing; pliant solids are provided with a firm support; and large, rigid substances are permitted to stand trial in their natural condition. In each instance, a roughly standardized candle flame is applied to one end of the prepared sample for a short time and when the sample ignites the rate of combustion along the major axis is determined. The substance is adjudged flammable if it catches fire readily at a comparatively low temperature and burns briskly.

The test for determining the flammability of solids does not possess the high degree of reproducibility we would demand of a method for assaying drugs. On the other hand, we feel that it is capable of demonstrating simply, rapidly, and above all, honestly, whether or not a solid substance is flammable. The actual performance of the test as we apply it in the enforcement of the Hazardous Substances Labeling Act will determine in short order whether our confidence in it, and in the other physical and chemical tests, is well-founded. **[The End]**

Laboratory Developments in the Division of Food

By DR. HENRY FISCHBACH

In This Speech Dr. Fischbach Discusses the Organization and Operation of the Division of Food, Bureau of Biological and Physical Sciences of the FDA. He Is the Director of That Division.

I AM SURE that this audience is fully conversant with the Federal Food, Drug, and Cosmetic Act and keenly aware of the amendments of the past seven years. This morning I will discuss briefly the Division of Food—its organization and operations as they reflect the broader responsibilities of the Food and Drug Administration and particularly those delegated to this division in the last few years. As these activities unfold, note that research methodology frequently holds the key to some of our more perplexing problems.

Generally, we in the Division of Food apply the physicochemical skills toward meeting our responsibilities. Our role is to develop and evaluate scientific facts which aid the Office of the Commissioner in reaching sound and meaningful decisions. The work of the division falls into three broad categories, which are best delineated by the names of the three branches: the food research brand, the pesticides branch and the food additives branch. To give you a better understanding of the inner workings of this division, I will describe briefly the functions of each group and, in passing, cite a few examples of recent laboratory developments.

The main functions of the food research branch involve food technology, the decomposition of foods and the composition of foods. My time today permits only passing reference to food standards. Most of the technical aspects associated with food standards are evaluated and developed by the food technologists in the food research branch.

In the field of food decomposition this branch has developed chemical indices which are unique to the detection of decomposition in

such foods as dried and frozen eggs, dairy products and fish. For several years various authentic packs have been prepared and studied for chemical criteria which would differentiate between sound and decomposed foods. Within the last year several seizures of decomposed fish and eggs were made on the basis of chemical criteria. When these seizures were contested, the courts found for the government.

Food Composition

Investigations on fats and oils are typical of our work on food composition. Several years ago we learned that abused cooking fats, resulting from prolonged heating at high temperatures, were toxic to laboratory rats. We initiated a project to study the fate of edible oils subjected to varying conditions of time and temperature. Shortly afterward, we were confronted with the spectacular outbreak in poultry popularly referred to as the chick edema disease. Since most of you are familiar with this project, I will merely say that the chemical isolation and the attempt to identify the chemical structure of the toxic component were and are being done in the division of food. The nutritional and pharmacological aspects of this problem are handled by the division of nutrition and the division of pharmacology. From this work, a specification was developed which forbids the use of fatty acids in foods unless they are free of the chick edema factor. At the moment, this specification is a bioassay procedure developed by our division of nutrition which involves a three-week chick assay. The food research branch is currently developing a physicochemical procedure which will screen many of the commercial fatty acids much more quickly than the chick bioassay method.

A recent example of a new laboratory development in food composition may pique your curiosity. For several years we had heard rumors concerning frozen fillets of "grouper" entering this country through the Gulf and South Atlantic ports and masquerading in our markets as a more expensive fish, the "red snapper." During the summer of 1960 we undertook to explore several laboratory approaches for exposing such deception. At the AOAC meeting in October of last year we announced a procedure which clearly distinguishes between various fish species used in frozen fillets. The reliability of this technique was demonstrated in a collaborative study and the method was adopted this year by the AOAC. The technique is a starch gel zone "electrophoresis." This terminology is meaningful to the scien-

tist and simply identifies the laboratory technique. To establish the authenticity of our starting materials, various species of whole round fish were submitted to the expert ichthyologists of the Smithsonian Institution. The various samples so identified were then subjected to the test. The technique requires little analytical time and relatively inexpensive equipment. To date, the procedure has been so successful that the Smithsonian Institution, itself, intends to use such an approach for some of their identification procedures. From a practical standpoint, the Food and Drug Administration already has consummated several seizures in the Gulf Coast area where it was found that "grouper" had in fact been substituted for "red snapper." As might have been expected, the development of this laboratory tool has stimulated corrective measures in the frozen fish fillet industry. The saving to the consumer is self-evident.

Pesticides

In turning to the pesticides branch, we find two major activities in their day-to-day functions. First, the review of formal pesticide petitions within the statutory limitation of 90 days. A small unit of competent chemists considers all of the technical aspects associated with the petition except for the safety considerations which are handled by the division of pharmacology. Secondly, the remainder of the professional chemists devote their time to methodology research. Besides devising better and more efficient methods in the areas covered by formal tolerances, they are also studying laboratory techniques for discerning the inadvertent or the intentional misuse of a particular pesticide on a raw agricultural commodity for which no tolerance has been established. As you all know, the pesticides in general use today are much more potent and effective than those of 20 years ago. This is reflected in such tolerances as one or two parts per million, or as low as 0.1 part per million. At these tolerance levels the respective pesticides are considered safe. Obviously, from a regulatory standpoint, techniques for measuring such tiny amounts of residues must be highly sensitive and precise. The more sensitive our techniques, the greater assurance we have of controlling the residues within the legal tolerances. Recently, the division of food laboratories and others have been devising and refining a new technique which promises to be another breakthrough in methodology. At the moment, we refer to this procedure as "electron capture" gas chromatography. In our hands this approach has demonstrated ultra high sensitivity even

when compared to other recent instrumental advancements. As a matter of fact, we can determine picogram quantities of some substances. A picogram is one trillionth of a gram, and there are 453 grams in a pound. Further, by this technique, we are hopeful of developing procedures which will require less time for the analysis of tiny amounts of residues in foods.

Passing quickly to the operations in the food additives branch, again we have a small unit of competent chemists to handle the technical aspects of food additive petitions except for safety, which again is the obligation of the division of pharmacology. I should say that those aspects which might involve microbiology or nutritional expertness are handled by the division of microbiology and the division of nutrition. Generally, the direct food additive petitions are processed by the coordinated effort of the technology experts in our food research branch and food additives branch. The remainder of the professional talent in the food additives branch is devoted to necessary laboratory work in the area of inadvertent food additives. I believe you will be interested in two recent developments in this phase of the work. In one of the early food additive petitions, we were confronted with a request for a tolerance of 200 parts per million of mineral oil in quality cuts of meat. The residue of mineral oil stemmed from the use of a new packaging process. Although the initial deficiencies in the petition regarding the fate of mineral oil in the body of man required some additional data from the petitioner, another unexpected problem had arisen with respect to petroleum by-products. Other investigators had raised the question of possible polynuclear contaminants in mineral oils and waxes. The term "polynuclear" is a generic designation used by the chemist and refers to some thousands of chemical compounds. Of these relatively few have been condemned as carcinogens. Consequently, we requested the petitioner to furnish an adequate specification for mineral oil to assure us of the absence of the carcinogenic type of polynuclear compound. We found the specification as submitted to us inadequate for such assurance. Since then, the industry and ourselves have explored various physicochemical techniques to satisfy the need for suitable specifications and methodology. Without burdening you with the research details, I am happy to say that at the AOAC meeting a few weeks ago we unveiled a straightforward procedure which is particularly designed to detect the carcinogenic type of polynuclear. Nearly all of the U. S. P. or N. F. mineral oils which we have tested by the new procedure meet

the requirements of the new test. We have not identified any carcinogen in the few that failed but rather an interfering antioxidant.

I might add that we have recent evidence that a similar approach may be successful for the same purpose in the paraffin waxes. We are quite enthused with these evolving laboratory techniques which can be used as realistic guards against harmful polynuclears.

Food Packaging Materials

As most of you know, one of our most perplexing problems has been the incidental additives from food packaging materials. Ingenious approaches have been recommended and studied both by industry and by the food additives branch. Without belaboring the many details of simulating food solvents, exaggerated temperature conditions, the multicomponent formulations, etc., the final parameter which appears practical and meaningful to the scientist for evaluating food quality packaging is an end extractability test of the finished packaging material. Many petition requests have been received in which different techniques and different equipment had been used for developing extractability data. Under such circumstances, it is extremely difficult to establish a uniform and acceptable limitation. Industry was so keenly aware of this problem that a new committee was established in the American Society for Testing Materials expressly for the purpose of developing a uniform extractability test applicable to flexible packaging materials. The ASTM requested advisory participation by the FDA, and the division of food has cooperated in this effort. Recently, the food additives branch developed a simple extractability cell which appears to meet the demands of this problem. Both the ASTM group and our own laboratories are greatly encouraged by the simplicity and the potential of this technique. Currently, the ASTM committee is testing the accuracy of this method when applied to various plastic and paper packaging materials.

In the allotted time I have been able to discuss the functions of the division of food only briefly. You may have noted that a strong thread of research methodology runs throughout the fabric of our activities. I am sure that this audience is aware of the robust trend toward more highly sensitive methodology. Often in the recent past this trend has been stimulated by sections of the scientific community not associated with foods. It is a truism today that as man reaches for the moon or for higher food production he finds his attempts for

greater technological advances tied to the development of ultrasensitive methods or tools of high precision. Further, it is axiomatic that the scientist in the food area will adapt and apply the newer instrumentation and techniques.

The new valid facts thus developed will give us all a better insight into our environment and the food supplies derived therefrom. Ignorance may be blissful but also shortlived. With more knowledge I am certain that wise and practical decisions can be made which will give us even greater pride and assurance in the purity and wholesomeness of our foods. **[The End]**

"NUMBER ONE" CONSUMER PROTECTION PROBLEM

"Vigorous control to assure the safe use of the multitude of chemicals in our food is our number one problem of consumer protection today," according to Mr. William W. Goodrich, Assistant General Counsel for Food and Drugs. Speaking before the National Conference an Antitrust Problems and Consumer and Investment Protection, held at the Justice Department, he expressed the opinion that there would be general agreement on this classification, at both federal and state levels.

Moving into the problem of determining safe levels of use for these substances, Mr. Goodrich described the task as "a formidable one," for which "strong and effective scientific resources are necessary before we can even begin." As to color additives, "We must prepare ourselves . . . to regulate the use of colors in a variety of foods at levels expressed in terms of parts per million."

State laws . . . Doubt as to the effectiveness of some state laws relating to additives was also indicated by Mr. Goodrich. "We have noted, with interest, the new Texas Food and Drug law, and the recent New York statute on the food additives problem. We see some provisions in them that may give the state agencies difficulties. As we read the Texas law, for example, a food additive must be shown to be a poisonous or deleterious substance to be adulterated. And the New York law seems to apply only to 'new food additives,' insofar as proof of safety is required."

And hazardous substances . . . On the subject of hazardous substances labeling under the Federal Act scheduled to become effective in February of 1962 "unless [the deadline is] extended by Congress," he noted that "there is some urgency in letting [federal officials] know of any problems that may have been created for state agencies as a result of [the federal] program. We are prepared to make any possible adjustment to accommodate the legitimate needs of state agencies as well as our own."

The Analysis of Drugs

By DR. FRANK H. WILEY

Dr. Wiley Is the Director of the Division of Pharmaceutical Chemistry, Bureau of Biological and Physical Sciences of the FDA.

WHEN I ASKED two of my associates for suggestions on the presentation of the problems of drug analysis to an audience composed largely of attorneys, they suggested that five minutes should be devoted to "reviewing the record," five minutes allotted for "pointing with pride" and the presentation should be terminated by "viewing with alarm." I suspect they have not completely forgotten the political conventions of 1960. Although the suggestion was intended to be facetious, I was amazed to find the outline of the subject fitted very well into the course they recommended.

Those of you who have a connection with the field of pharmaceuticals are probably as impressed as I am with the tremendous advances which have been made in the development of fine pharmaceuticals in the past quarter of a century. If you review the drug compendia of the late thirties, you will find that most of the pure chemicals listed therein represent adjuncts to be used in formulating dosage forms of the drugs. Many of the active pharmaceuticals were derived from vegetable or animal sources, and, in most instances, were in the form of the ground whole plant material or very crude extracts of plant or animal tissue. The age of chemotherapy was just beginning and ready-made solutions and suspensions for injection were just being recognized by the compendia.

Synthetic Pharmaceuticals

Today, most of our potent pharmaceuticals are made synthetically and are of a relatively high degree of purity. Where the chemical laboratories have been unable to synthesize products with equal or better medicinal properties than those provided by nature, we still rely on vegetable and animal sources. However, instead of using the

whole plant, or a crude extract thereof, we have now isolated and purified many of the active principles. With drugs of this type available, the physician can administer medicinals with a greater degree of confidence and precision.

Twenty-five years ago, the pharmaceutical and medical professions were pointing with pride to the advances made in the preceding two decades. They had produced hormone preparations like epinephrine, insulin and the sex hormones with which they could treat many conditions. A number of analgesics had been developed to alleviate pain. Serums, vaccines and antitoxins had been developed to immunize against diseases of various types or for the treatment of those conditions if they were contracted. Their pride in their achievements is understandable. We are still using many of the products they developed but in much improved forms and with greater confidence in the results to be achieved. But all of this is probably prologue. In 1985, our successors may marvel that the human race was able to survive with nothing but sulfa-drugs, antibiotics, hormones and synthetic medicinals to aid them in their fight against disease.

New Procedures for Drug Analysis

Our progress in the production of new drugs has been equaled by the development of new procedures for their analysis. The routine analytical procedures of today would have been deemed impossible by most of the pharmaceutical chemists of the thirties. The development of infrared and ultraviolet spectrophotometers, polarographs, nonaqueous titration techniques, etc., has given the analytical chemist tools with which he can make accurate measurements with milligram or microgram quantities of material. But here we come face to face with one of our main analytical problems.

In the application of these analytical tools, we are measuring with precision some chemical or physical property of the substance under examination and hoping to relate the data obtained to the quantity of the single compound to be determined. These chemical and physical properties are not always specific for a single chemical. Usually, other substances with similar chemical configurations will exhibit the same or similar properties. Thus, the results of the analytical measurement may represent the combined effect of two or more substances. For the results to be completely reliable, the analyst must know that substances which could interfere with the determination are not present in the preparation under examination.

A number of procedures are available for acquiring this information. One or more identification tests, as required, can be developed to show that the product contains the substance declared on the label. Tests can be developed to limit the amount of similar compounds which will be permitted. The development of paper, column and vapor phase chromatographic techniques has permitted the chemist in many instances to separate the material in which he is interested in a pure form before he applies the technique for its final estimation. Unfortunately, the application of these procedures to identify the drug, to indicate its degree of purity and to isolate it so that its concentration can be determined with accuracy usually takes far more analytical time than the final determination of the amount present.

Here we encounter our second major problem in the development of methods for drug analysis; namely, the compromise between the ideal and the practical. Usually the attitude of the analyst, in this respect, is colored by his own peculiar needs. There has been a tendency for the control chemist in the manufacturing plant to adopt highly simplified methods for the control of production. This probably is the result of constant and understandable pressures which are exerted to cut the costs of operation. Since he has available to him information other than that obtained in the assay of the finished product, I agree that considerable simplification of analytical controls can be effected without sacrificing safety. For instance, the control chemist knows the purity of the basic drug which was used; he knows the nature and purity of all inert ingredients in the formulation; and, he can assure himself that none of the inert materials will interfere with the determination of the drug by a simplified procedure.

On the other hand, the enforcement chemist must rely entirely on the results of his analysis of the finished product. Not having the knowledge of the nature of the components used in making the pharmaceutical nor information on the purity of these starting materials, he must use analytical procedures which give him accurate information on the amount of the drug present and assure him that the values obtained have not been influenced in any way by the presence of other substances in the formulation.

As you may have surmised, the development of analytical tests and assays for basic drugs does not represent too great a problem in most cases. Here we are dealing with relatively pure chemicals and usually our needs can be satisfied with identity tests, to safeguard us against labeling errors, and an assay and tests to indicate the exact

purity of the drug. Occasionally, when the conditions of manufacture make it possible for related compounds to be present, we need specific tests to limit the amounts of these impurities.

However, when these basic drugs are used in making tablets, solutions, syrups, suspensions, etc., where they are mixed with a variety of inert materials to make the finished product more stable, usable or palatable, we then complicate the analytical problem. These complications reach their ultimate degree when the analyst does not know the nature of the materials used.

Prior to the enactment of the Food and Drugs Act, the United States Pharmacopoeia and the National Formulary were primarily compilations of information on drugs which were useful to pharmacists, physicians and pharmaceutical manufacturers. Their inclusion in the Act gave them an entirely new status as legal standards to be used in the enforcement of the law. Since that time, the committees charged with the revision of these compendia have made every effort to revise these compilations so that they would be adequate for this purpose.

Section 501(b)

Section 501(b) of the Act specifically states that compliance of drugs with the standards set forth in these compendia shall be determined by application of the tests and assays provided therein. This leaves the enforcement chemist with no choice of analytical procedure. Any evidence he presents in court to show that a violation of the law has occurred in respect to a drug named in the compendia must be adduced through the use of the official procedures. Should the defense attack the evidence by attempting to show that the assay procedure was inadequate or inaccurate, the enforcement chemist would probably be called upon to defend the validity of the method. If it happened to be a procedure in which he had little personal confidence, his lot would be an unhappy one indeed. Thus the enforcement chemists must not only use the methods adopted by these compendia but they must also, through cooperation with the committees of revision, assure themselves that the techniques so adopted can be defended in court should the necessity arise. While members of the Food and Drug Administration staff do not serve on these committees, it has been our policy to give them every possible aid in perfecting these standards. Whenever our experience dictates that a proposed method of analysis is inadequate or a proposed standard is unenforceable, we feel obliged

to give them the reasons for our conclusion and aid in developing better procedures or more realistic standards.

As indicated previously, I am not concerned when the control laboratory of a manufacturing plant adopts a method of assay which is less exacting than the official procedure. If the control chemist has additional information and his knowledge of the manufacturing operations assure him that a satisfactory analysis by a simplified technique will guarantee a legal product, he is justified in effecting this saving of time. However, when he insists that this simplified method of analysis is also suitable as a part of a legal standard, I then become concerned. The decision to charge an individual or a firm of committing a violation of the law cannot be made lightly. It should be based on information whose accuracy is of the highest order. A member of one of the committees recently asked me to give him my criterion for the acceptability of a method of assay for inclusion in an official monograph. I replied that it should be the best procedure we are capable of devising. When we consider the seriousness of the consequences which may result from its application, I think we can settle for no less than the best.

The two problems I have discussed are intimately related. They are probably more of an administrative than a technical nature. Of course we do have our purely technical problems. New drugs and new combinations of drugs present us with new problems every day. I am constantly impressed, however, with the ability of the analytical chemists to take apart anything that the production people can mix together. I have complete confidence in their ability to eventually achieve the solution to any technical problem presented to them. If those of us who are responsible for the administrative aspects of the establishment of drug standards are equally adept, I see nothing in the field of drug analysis which we need to "view with alarm."

[The End]

PRODUCT LIABILITY

Res ipsa loquitur . . . In an action for damages for injuries sustained by the explosion of a carbonated beverage bottle, the testimony of the plaintiff that the exploding beverage bottle was handled properly after leaving the control of the defendant was sufficient to form a prima facie case for the application of the doctrine of *res ipsa loquitur* even though some other testimony of the witness was shown to be false (*Bonura*, Ct. of Appeal, 1st Circuit, La., FOOD DRUG COSMETIC LAW REPORTS ¶ 22,692).

Report from the Division of Pharmacology

By JAMES R. CRIBBETT

Mr. Cribbett Is Assistant to the Director of the Division of Pharmacology of the Bureau of Biological and Physical Sciences of the FDA. In This Speech, He Reviews the Work of the FDA in Measuring the Contamination of Food from Radioactive Fallout.

WITH THE DUST of the recent Russian atomic tests settling on this nation and the rest of the world, it may be useful to review the work of the Food and Drug Administration in measuring the contamination of our food supply by this man-made radioactivity. The technical guidance of these investigations is centered in the division of pharmacology under the direction of Dr. Edwin P. Laug, chief of our radioactivity branch. To Dr. A. J. Lehman, director of the division, goes credit for recognizing, in 1949, the future importance of this work and for initiating training of one of his staff members at Oak Ridge. A first, our efforts were directed toward the development of civil defense capabilities. In 1951, training of our own people for defense against radioactive contamination from nuclear warfare was begun by the Bureau of Field Administration, and civil defense schools were organized under the leadership of Mr. W. B. Rankin. At that stage, ten years ago, we were faced with the problem of coping with the wholesale and massive contamination of our food and drugs that could result from nuclear attack. The contamination resulting from a few tests of small bombs was then so slight that we could ignore it.

But the tests continued. And the bombs grew larger. In 1954, came the awesome test in a remote area of the Pacific of our first hydrogen bomb, "Operation Castle." And with it came the incident of the Japanese fishing boat, "The Lucky Dragon." Ash from that explosion fell on the fishermen and on their catch of tuna. We began an immediate program of monitoring at the ports of entry all tuna and other fish caught in the Pacific. Our instruments at that time were

designed for use in civil defense, but they did prove to be useful for monitoring. During the months of surveillance which followed, only two or three fish showed evidence of fallout. Subsequent analyses by the Atomic Energy Commission revealed that the contamination was of a very low level and confirmed our conclusion that our supply of fish from the Pacific was suitable for food.

Atomic Testing Necessitates Investigation

We in Health, Education and Welfare and scientists throughout the world had by that time realized that continuation of atomic tests would call for investigation of the extent of man-made radioactivity in our food supply and its effect upon our health. In 1957 the division of pharmacology began examination of foods for total beta activity. Each of the radioactive elements has a characteristic type of emanation. For our purposes we can confine our attention to the two general classes of beta and gamma radiation. Their effect on the body is the same, but different types of instruments are needed to measure them.

From our studies of total beta radiation we have been able to identify those foods which will be of primary concern should fallout radioactivity rise markedly above the current figures. These are the leafy vegetables, the forage crops such as alfalfa and hay, oysters, clams, tea and dairy products. The greater contamination of the leafy vegetables and of forage seems to be related to their great surface area as compared with their weight. This observation leads to the deduction that, at present, contamination of crops results more from the direct raining down of the particles in the air than from absorption of the fallout already deposited on the ground.

The fact that a large part of the man-made radioactivity of food is present on the surface of food accounts for our finding that the commercial processes of washing, peeling, etc. of vegetables in preparation for canning or freezing reduced the contamination by about 50 per cent. A number of "before and after" tests on tomatoes, spinach and the like are the basis for this figure. The activity in flour is reduced to one-sixth to one-tenth of that of the wheat from which it is milled. In the case of tea, about 80 per cent of the activity remains in he leaves when the tea is brewed.

We have found low levels of contamination in fruits, meat, poultry, eggs, tomatoes and root crops such as potatoes and carrots.

Although total beta analyses enable us to make usable estimates of specific and important elements such as cesium-137 and strontium-90,

more precise values are obtained with other instruments and techniques. Our division now uses the gamma spectrometer which enables us to make direct measurements of iodine-131 and cesium-137 without preliminary processing of the material. But for strontium-90, figures can be obtained only by preparation of the sample with painstaking chemical procedures. At present, strontium-90 analyses require two or three weeks, and we do not have any significant reduction of this time within sight. Our interest in strontium-90 comes from the fact that it is deposited in bone and because its activity is reduced only by half in the course of 27 years. It is therefore essential that we keep the strontium-90 content of our food within levels which scientific judgment considers acceptable.

Scientific Opinion of Radiation Effects

I stress the word "judgment" because we do not have precise knowledge of the effect on our bodies of extremely small amounts of added radioactivity. Scientific opinion, however, is that radiation does have an adverse effect no matter how small it is and even when we are unable to measure the effect. This assumption is used by the government for planning purposes. In arriving at a judgment, we should not forget that exposure to ionizing radiation did not begin with the atomic bomb. Since the beginning of life on this planet, we have been exposed to the radiation of cosmic rays and to radioactivity from the soil and the materials of our buildings. Even our food and bodies have always carried a significant amount of the naturally occurring radioactive potassium-40.

Several years ago the Federal Radiation Council was established to deal with this problem and those related to it. The chairman is the Secretary of Health, Education and Welfare, and the members are the Secretaries of Defense, Commerce and Labor and the Chairman of the Atomic Energy Commission. The question before the council could be expressed in these words: "Knowing the amount of 'background' radiation from natural sources, what additional small amount of radiation from medical and industrial uses and from fallout, can be judged acceptable?" The council recently gave a partial answer to this question when it issued guidelines for the fallout elements iodine-131, strontium-89 and strontium-90. Three levels of activity were given for each element and the character of action to be taken was outlined. The levels are stated in terms of radioactivity to which an individual would be exposed daily from air, water and food during a year. From

this it follows that the Federal Radiation Council guidelines are not specific tolerances relating to the specific radioactive content of an individual lot of a specific food (whether a truckload of apples or an elevator full of wheat). Figures which would be applied to these must be developed in the context of the amount of radioactivity which the population may be expected to receive from all other sources during a year's time. We have not yet issued regulations setting specific tolerances for radioactivity in food because at the relatively low levels of contamination thus far encountered, the Federal Radiation Council guidelines are sufficient. However, if it should become necessary, we will establish formal tolerances under the Food, Drug and Cosmetic Act.

Strontium-90 Content in Average Diet

We have recently investigated the strontium-90 content of the total diet in the Washington, D. C. area. Foods representing the diet of a 19-year-old boy were purchased in May and again in August of this year from representative retailers. The foods which required preparation were cooked in the usual way. The beverages included coffee, tea, milk, carbonated drinks, as well as water. From assays of these foods we estimate the adult dietary intake of strontium-90 in this area to be 11 picocuries a day. (The picocurie is also referred to as a micromicrocurie). This is well within the range of acceptable intake recently published by the Federal Radiation Council.

We have now completed radioactivity analyses of well over 6,000 samples of a wide range of foods. In carrying out this work, the division of pharmacology is indebted to the bureau of field administration and to our district offices for the collection of the samples and the preliminary processing of most of them. We are also grateful for the collaboration of the bureau of program planning and appraisal in organizing the surveys. Ten of our district laboratories are now equipped for total beta and strontium-90 analyses, and are beginning to increase the scope of our surveillance.

Public interest in the healthfulness of our milk supply arose during the Russian tests of last month. Fallout from those tests resulted in an increase in the iodine-131 content of milk in some areas of the country. In commenting on this, a joint statement by the Food and Drug Administration and the Public Health Service said, in part:

> It should be emphasized that the quantities of iodine-131 that have accumulated in milk to date (Oct. 26) do not exceed the Federal Radiation Council guidelines for yearly consumption under normal peacetime conditions. . . . Of course if a critical situation developed, the Federal Government has authority

under the Food, Drug and Cosmetic Act to seize interstate supplies of milk and other foods showing high radioactivity. State and local health officers have similar authority to deal with foods and milk not in interstate commerce. However, such actions are not in prospect in view of the levels of activity currently being found.

I am glad to report that continued surveillance by FDA and PHS during November shows no reason for concern.

To turn now to another part of the activities of the division of pharmacology. The Food Additives Amendment has greatly increased the volume of our work, as it has that of the food and packaging industries. Persons with food additive problems frequently find it advantageous to confer with our division on the type and extent of data required to establish that the additive can be used safely. These conferences are also valuable to us, because our visitors can describe the technology of their industries and give us a clear picture of how and why the additive is to be used.

Since it is not uncommon for Dr. Lehman to have three or four of these conferences in a single day, let me make some suggestions on how a conference can be arranged to the greatest benefit of you and of our division:

(1) Our visitors can present well-organized discussion of the technology of the problem and the reason for use of the additive; a clear description of the chemical nature of the additive; a summary of the pharmacological data available; and information on the amount of additive which will become a component of food.

(2) It is helpful to us (but not essential) to receive a summary on these points about a week before the conference. A summary has its greatest value when it consists of just a few pages. Unfortunately, we do not have time to review voluminous data either preceding a conference or during it. The detailed support of the points in the summary can be reserved for the food additive petition itself.

(3) The conference should normally take no longer than an hour. While exception to this rule can be made when the subject is of industry-wide impact, we generally have to request this limitation in order to make time available to others who seek our views.

(4) When the additive is a mixture or a product formed by chemical reaction of a number of materials, we need a precise chemical description of the final additive. We are conversant with the chemical composition of some of the trade-named articles which are widely used in the container and packaging industries. But we do not know

the composition of many other articles sold under trade names. If the supplier hesitates to reveal the chemical identity to you, he may still be willing to disclose it in confidence to us. Obviously, if this procedure is necessary, it should be completed before the conference is held. Some of our conferences have ended on an inconclusive note simply because the person who proposed the use of the additive had no information whatsoever on its chemical nature.

(5) Our primary function is to discuss the pharmacological and safety data for the additive. When questions are raised about FDA's administrative policy, we are glad to answer them when the policy on the subject is well established. When questions require new policy decisions, or touch on differing interpretations of the amendment or its regulations, we believe our visitors should consult the food additives group of the Commissioner's office.

With some assistance from you in supplying relevant information on proposed additives, we can more readily undertake consideration of new problems. **[The End]**

HEW RELEASE

The Food and Drug Administration cautioned an estimated 75,000 distributors of products of the Nutri-Bio Corporation, Beverly Hills, California, that the legality of the basic sales promotion materials used by the parent firm has been challenged by a November 24 seizure action against Nutri-Bio in the District of Columbia.

FDA warned the Nutri-Bio distributors that continued use of Nutri-Bio sales material alleged by the government to be false and misleading may subject them to federal prosecution and their merchandise subject to seizure. The material includes the Nutri-Bio General's Manual, Sales Manual and other literature furnished by the corporation.

FDA said it was making this statement because a letter issued on November 27 to top-level sales personnel—called "Generals" and "Group Coordinators"—by the company erroneously states that the D. C. seizure action is based solely on the unauthorized action of a local distributor and in no way involves the parent company.

The FDA case, filed in the D. C. Federal Court on November 24 charged that four Nutri-Bio food supplements were misbranded by false and misleading claims for treating and preventing a long list of serious disease conditions. The labeling material containing the alleged false statements included sales manuals, program kits, testimonials, records, filmstrips and Nutri-Bio newsletters shipped by the Nutri-Bio Corporation, Beverly Hills, California.

Commenting on the company's letter, Malcolm R. Stephens, Chief of FDA's Bureau of Enforcement, said:

". . . While this matter is pending it would be unfortunate if a misunderstanding of the nature of the Government's charges should result in widespread violation of the law by sales personnel."

Bacteriology and Microscopy

By DR. GLENN G. SLOCUM

Dr. Slocum Is Director of the Division of Microbiology of the Bureau of Biological and Physical Sciences of the FDA.

IT IS UNDOUBTEDLY TRUE that the food and drug supply in the United States is the safest and purest in the entire world and throughout history. This statement represents a real tribute to the food and drug industries and regulatory officials alike and to the progress made through their combined efforts. Obviously, many problems remain to be solved if we are to continue this progress and new problems arise as technological advances and changes occur in food and drug production and distribution. This discussion deals with some of the microbiological problems with which we are presently concerned.

Water and milk have become virtually insignificant as a source of human illness. Advances in technological research and in the development and application of control techniques have eliminated the substantial disease hazards that water and milk formerly presented. Food-borne disease has not decreased similarly but appears to have continued at the same level or, perhaps, to have increased slightly during the past one or two decades. Each year, some 200 to 300 outbreaks consisting of about ten to 12 thousand individual cases of food-borne diseases are officially reported by states and cities to the Public Health Service. This level greatly exceeds outbreaks and cases traced to water and milk.

Incomplete Reporting

There is sound evidence to indicate that investigation and reporting of food-borne disease is grossly incomplete. For example, one state reports about one-third, and some five or six states nearly two-thirds, of all of the outbreaks and cases officially recorded. Nearly half of the states report an average of less than one outbreak a year, while few cities tend to report outbreaks. Obviously, such unequal distribution of reported food poisoning cannot represent the true state of affairs.

The incidence of food-borne disease must be many-fold the levels reported. Several scientists working in this area have estimated the probable incidence to be on the order of 300,000 to 1 million cases a year. The problem then is quite formidable and represents a major challenge to industry and regulatory officials since food poisoning must be regarded as preventable.

Interstate foods have not been implicated frequently in outbreaks of food-borne disease. Nevertheless, experience of recent years has removed any complacency we may have had regarding interstate food products. Three dried food products were implicated in outbreaks of salmonellosis in children or in hospitalized patients. Discovery of each outbreak was largely fortuitous and each nearly escaped detection. Substantial outbreaks of typhoid fever in several states and Salmonella reading infections throughout the country in 1956 and 1957 had the characteristics of common food source incidents but the sources could not be discovered in spite of intensive investigation by state and federal officials. Recently, it was necessary to recall a commercial hollandaise sauce found to have caused 27 cases of salmonellosis in California.

We believe, also, that it is significant that Public Health Service statistics show a seven-fold increase in proven cases of salmonellosis between 1948 and 1956—from less than 1,000 to over 6,700 cases a year. The source of infection in the majority of these cases is never established. Many authorities believe that most of these cases are food-borne. Evidence continues to accumulate that salmonellae are much more prevalent than formerly realized. Since they are fecal organisms their presence in foods indicates fecal pollution at some stage of production. We believe it is important to study and evaluate more extensively and thoroughly the bacteriology of food production, product by product and plant by plant, to discover and eliminate hazardous or potentially hazardous products and practices. Special emphasis needs to be placed upon the increasing variety and volume of "convenience" foods, so often consumed without thorough cooking during home preparation.

Staphylococcal intoxications, caused by toxin preformed in food during growth of certain staphylococci, remain the major form of food poisoning in the United States. While interstate foods have not often been implicated in staphylococcal food poisoning, again recent experiences with outbreaks involving dried milk and both domestic and imported cheeses have pointed up the need for research in this

area. In addition to basic research on development of methods to detect food poisoning staphylococci and the toxin directly in food products, the division is engaged in a nation-wide study of the numbers and types of staphylococci in manufacturing milk to serve as a basis for further control efforts.

Two new micro-organisms have been added to the list of food poisoning agents, and one, *Clostridium perfringens,* have been implicated in a few outbreaks in this country. We believe this organism is responsible for many outbreaks and plan to search for *Clostridium perfringens* and another anaerobic bacteria in our food supply as a potential measure of safety and sanitary quality.

New Facets of Old Problems

Two outbreaks of botulism within the past year or two illustrate newer facets of old problems with which we must be concerned. Commercially canned products have been virtually eliminated as a source of botulism, but the recent outbreaks have involved frozen and refrigerated foods. Two frozen chicken pot pies baked and left inadvertently in a warm oven overnight, were warmed and tasted by two persons the following day. Although the pies were recognized to be spoiled upon the first taste, both individuals developed typical symptoms of botulism but, fortunately, recovered. In the second outbreak, the victims were not so fortunate; two died. This outbreak was caused by *Clostridium botulinum* type E in smoked fish packed under vacuum in plastic bags. We demonstrated experimentally that the organism produced toxin in smoked fish held with or without a vacuum for five days at 50° F but failed to do so at 40° F in 30 days. However, a recent report of toxin formation by this organism at 38° F after slightly longer holding periods causes real concern regarding the safety of refrigerated foods in which the storage life is greatly extended by newer packaging methods or preservatives which inhibit surface spoilage or alter conditions so that normal indices of spoilage are not evident.

Oysters and clams from polluted waters have been incriminated this year in the transmission of infectious hepatitis. The current high incidence of this disease directs attention to the possibility that foods may serve as a vehicle for the spread of hepatitis and other enteric viruses through insanitary practices which permit fecal pollution. Indeed, two local outbreaks of infectious hepatitis have been traced to infected food handlers by health authorities during the past few months.

To a large extent, the food sanitation programs of FDA have employed visual inspection methods and microscopic analytical techniques which reflect the physical cleanliness of foods and factories. These procedures will continue to be important in our programs and, in fact, need to be extended to keep abreast of changes in raw material control and in food processing technology. Although such methods have resulted in marked improvement in food plant sanitation, they cannot assure the bacteriological cleanliness of processing operations or of food products. The shift to increased production of nonsterile prepared foods, often in large interstate plants, makes it imperative that we judge the safety and sanitary quality of food production more and more upon a bacteriological basis.

Since the numbers and types of micro-organisms in food products vary widely with variations in raw materials, processing procedures and sanitary conditions and practices, thorough and competent bacteriological studies in each food plant are essential to detect and eliminate sources of contamination and to permit interpretation of the findings on finished products. Modest increases in the staff of the division, and the addition of bacteriologists in several of the field districts, have permitted a beginning in our program of bacteriological evaluation of food plant sanitation.

Ultimately, emphasis by industry and regulatory officials upon bacteriological control of food production should be most effective in reducing the risk of food-borne disease.

Microscopy Serves as Important Tool

As previously indicated, microscopy continues to serve as an important and unique tool for measuring many forms of contamination, decomposition and insanitation in food products and establishments. Application of these methods by regulatory agencies and industry in conjunction with sanitary inspections, has resulted in substantial improvement in the cleanliness of food plants and products. Many problems remain. We still compete with insects and rodents for our food supply (in the field, in storage and in processing plants) and must be eternally vigilant against food contamination resulting from their activities.

With our current staff and facilities it is difficult to keep up with problems arising in connection with many commodities, new and old, with improvements in raw materials control and with changes in

processing technology which may affect the microscopical findings and interpretations.

Specific identification of ingredients and contaminants of food and drug products requires considerable attention. For example, the identification of an insect species by examination of the insect parts in a food often indicates the point of infestation in the field, in storage, or in an insanitary plant. We are also currently concerned with the detection and identification of Crotalaria tissues in cereal and seed meals contaminated with the toxic Crotalaria seeds.

Probably the foremost application of microscopy in current enforcement activities is to provide proof of the interstate origin of prescription drugs sold illegally and to identify counterfeit drugs. Microscopic, physical and ballistic types of tests have proven quite effective in identifying the manufacturing source of such drugs.

Further applications of microscopy in enforcement activities are limited only by available manpower. **[The End]**

FDA PAMPHLET

Food shoppers who are interested in laws that protect their health and pocketbooks can get useful information from a new pamphlet, "What Consumers Should Know About Food Standards," issued by the Food and Drug Administration.

The FDA standards regulations stand back of the quality and integrity of hundreds of major food items in the American diet. They specify what ingredients and processes may be used and the information which must be given on the label. Development of the standards is a cooperative activity on the part of government, industry and consumers. Factual information from these sources is the basis of the standards.

Whenever "such action will promote honesty and fair dealing in the interest of consumers," says the Federal Food, Drug and Cosmetic Act, FDA is authorized to set standards of quality, indentity and fill of container for any food, except most fresh and dried fruits and vegetables which are exempted.

"For example," the pamphlet states, "the standard of indentity for fruit preserves and jellies requires not less than 45 parts by weight of fruit or fruit juice to each 55 parts of total sweetening ingredients. . . . At the public hearings, which preceded the writing of this standard, cookbooks 200 years old, as well as current ones, were introduced in evidence to show that pure jam is a product made from approximately equal parts by weight of fruit and sugar."

The 12-page pamphlet is illustrated with photographs showing some of the scientific tests FDA makes to check samples of food products against the standards. The last page lists the food for which standards have been established. It is for sale by the Superintendent of Documents, United States Government Printing Office, Washington 25, D. C.

Citizens Advisory Committee

By DR. GEORGE Y. HARVEY

This Address Was Presented at the Food Law Institute Dinner at the FDA-FLI Conference. Dr. Harvey Is the Chairman of the Second Citizens Advisory Committee.

LAST WEEK I received a letter from the editor of a trade publication which was quite interesting. I don't criticize this particular editor or his publication because he only followed the mores of the times. He asked that I send him a copy of the speech I am going to make tonight several days ahead of delivery because "being a monthly publication we must work well in advance to meet our tight production schedule." Let me assure you that what I have to say tonight will not be of that order of importance. I hope that what I shall have to say several months from now will be of some very real significance, but that will be after I have had the opportunity in cooperation with fellow members of the Advisory Committee to examine carefully, and in important detail, the operations of the Food and Drug Administration.

Some years ago when I was trying to keep up with the parade here in Washington I commented on more than one occasion that I was so busy fighting fire that I didn't have time to look for the cause. I welcomed appointment to this Committee because it presented an opportunity to slow down and take the time to study one subject carefully. Perhaps just this once I shall be able to say that I know what I am talking about; or at least I shall not be able to protest lack of time and opportunity.

Insofar as I am personally concerned, that will be the key to the Advisory Committee's work. We are not going to proceed as though we were double parked. One of the causes of present problems in the world is the speed with which we move. We don't know where we are going because we don't know where we have been.

No significant statement can be made until the Committee has done a thorough job and the fine able people with whom it is my honor to associate have had an opportunity to reach some judgment in common—a balanced judgment reflecting the various points of view and the philosophical backgrounds of this carefully selected cross-section of American life. It is my hope that we can avoid any hurried approach that might result in faulty judgment.

The Committee has gone to work and is attempting to do a worthwhile job. Not one of us went on this Committee with any mental reservation or purpose of evasion. We are not going to hurry and in the light of this whole situation it seems appropriate to quote that most quotable of all modern Americans, Alben Barkley, who said, when sorely pressed in an adjournment drive on the floor of the Senate late one night: "O, tempore; O, mores; oh hell."

Truly, it would be unseemly of me to attempt to discuss the projected study of the Advisory Committee in other than broad outlines and an introduction of myself to you by way of expression of a few of my own guiding principles. Call them prejudices if you like.

Six years ago, Secretary Hobby appointed a Citizens Advisory Committee to make a study of the Food and Drug Administration, and its members did a very excellent job. Their report has been most useful. Before and since that time, there have been a number of other studies and surveys by other groups and agencies both for general and special purposes. These surveys have been so numerous that the only comment of a friend of mine, when he learned the purpose of my recent visits to Washington was, "You, too?"

I referred earlier to finding the cause of the fire and it is in this area that the current Committee can render useful service by probing into the causative factors. The Food and Drug Administration has been embroiled in more than the ordinary run of controversy for some years. A more stabilized atmosphere is desirable and it will be to our great credit if we can contribute toward it in some measurable way.

A matter of very real concern to the Committee will be the efforts of the Administration to keep industry and the general public fully informed of the law and operations under it.

The former Citizens Committee found "the existing organization of the FDA is inadequate in number and talent to develop and direct the program and methods of education of the general public and in-

dustry." Efforts have been made to correct this situation and the present Committee will attempt to learn how effective these efforts have been.

I approach the subject with the impression that much of this field remains to be put to the plow. It is not an easy task and I do not expect that any committee study can produce a detailed operating plan guaranteeing results. Too much depends on administrative control, available talents, etc. Let me express a personal view here on organization. Organizations are easy to plan and organization charts are fairly simple to prepare. But, that is only the beginning—only the facade. The remainder is people and it is in the selection of people that the major responsibility for success or failure of any endeavor lies.

The kind of education most needed appears to involve down-to-earth, matter-of-fact understanding with industry just as much as a general growth of knowledge on the part of the public as to the role and responsibility of the Food and Drug Administration.

Probably a higher development of understanding will go far toward avoiding the recurring controversy which has characterized the recent past.

It cannot too forcefully be said also that this burden is not entirely that of the government. The segments of American business with which the FDA is in constant contact must extend a willing hand.

There are many highly technical scientific problems involved in the administration of the food and drug laws, but also the Food and Drug Administration has a great deal in common with many other branches of the government, and these in turn are related to startling new developments in the social and economic life of the world. All acute social and economic problems tend to become political issues. In the last few decades social and economic problems have generated a plethora of political issues with which we have had no experience. Most of these problems are not peculiar to the United States, but certainly the political traditions of the United States furnish the best background in the world for handling them. Our system is most directly responsive and responsible to the people.

It is staggering to note all the changes in the way of life that have occurred in this century. It is almost safe to say that we have made as much progress this century as was made by man in all his prior history. Change has been very rapid in all fields. Education has felt it and has experienced real difficulty in keeping up. A few days ago

a group of us in the faculty were discussing the development of a new university program and somebody remarked that most of those present are teaching courses not even included in a college curriculum 40 years ago. As a matter of fact, the only man present whose current course offering antedated 1925 teaches Roman history, and he was there because he is the dean.

Bringing all of this down to the Food and Drug Administration, the first Federal Food and Drugs Act was enacted one year before I was born, and I do not regard myself as competing for Methuselah's record. This dinner is given by the Food Law Institute. Fifty-five years ago there was no food law. Your profession, as a specialty, is new in this century.

Lord Coke and Dr. Blackstone never heard of general laws intended to protect the food supply of their nation or most of the other legal problems which currently call for our attention. Too many people are inclined to the view that we should brush aside all our traditions and experience not only in the law, but also in the administration of government, as not applicable to this rocking, rolling, sometimes hysterical modern world, but the principles long established and the traditions of governmental administration built up over the centuries and greatly refined in our own history must serve as the counterbalance to preserve the best political system and legal system ever devised by man.

Let me raise a question with the legal profession, though. Have we really examined these new fields from a philosophical standpoint in an effort to develop basic principles? All this new field or regulation which intermingles the legislative, the executive and judicial functions under one hat has presented some difficulties which we seem to have handled on a short-range basis. Have we been doing business with too much heat and too little light? Should we not now begin to look at the basic nature of the problems involved?

On the technical side, the situation confronting the Food and Drug Administration has changed in a fashion and to a degree that would have startled most of the scientists in 1906. Dr. Wiley and his associates were concerned at that time with removing from the food supply of the nation, health-destroying and death-dealing impurities. Of course, this will always be a major concern, but one of the acute problems today is quite the opposite: the addition of health-giving and life-extending chemicals to natural foods and the highly complex questions incident thereto.

What were once purely local problems now take on a national significance. Not too many years ago it became necessary to meet a public clamor for regulation of weights and measures. This was a local retail problem and became the natural responsibility of local government authority. But now prepackaging of commodities that move in interstate commerce out of reach of the local arm of the law has called forth a public demand for increased federal supervision. Attention has been called to practices which seem to be for the purpose of cheating the purchaser and in such fashion as to render him helpless. Just how far the government can go in this field and how much can be accomplished by governmental action and by what method remains to be seen.

The responsibilities of the Food and Drug Administration seem to separate into two general categories:

(1) Those areas, such as additives, where the government must take the total responsibility because the purchaser is helpless to protect himself.

(2) Those areas where the purchaser can and, in all reality, should accept the normal responsibilities of an alert buyer.

Government can see to it that the butcher uses an honest scale, but it is up to the purchaser to see that the butcher does not weigh his thumb with the chops. However, the courts long ago stipulated the position of the ordinarily prudent man and it appears now that government must assume that degree of responsibility which will enable the ordinarily prudent purchaser to get a fair deal without using a slide rule.

Government has a very real responsibility to the people, and must meet that responsibility in the most realistic way possible. Secretary Ribicoff in establishing the Citizens Advisory Committee stated as its number one objective "To determine what would constitute reasonable and adequate protection by the Food and Drug Administration of consumers." This is no simple task, and this Committee cannot expect to produce a final and absolute answer which will last until the end of time any more than Dr. Harvey Wiley and his associates could have foreseen the major problems now confronting the agency which they established.

The business community also has a responsibility to itself as well as to the public. Business firms of the significance and scope of operations as we now know them must continue to live beyond one generation. This again is a development which has come about so rapidly

that probably many people engaged in business have failed to grasp the significance of longevity of a corporation. The stock in trade of any business dealing with the public is 90 per cent reputation.

A cigarette manufacturer 35 years ago advertised his product with the slogan "Not a cough in a carload." Finally so many cigarette makers got in the medical act that the same manufacturer advertised "Just a good smoke. We are tobacco men not medicine men."

Producers of foods and drugs are not peddling cigarettes and owe the public just a little more responsible attitude. On the one hand the public is entitled to it and on the other hand, if their ears are as keenly attuned to the jingle of the cash register as they should be, ethical businessmen can't afford less.

Recently, evidences of the fast buck approach have been found in the food markets. I speak from experience here. I am the family buyer. Haggling is my recreation. Otherwise, my bank account would be larger and my junk pile smaller.

Tactics of this kind tend to encourage consumers to buy "Brand X." Why pay the big advertising bill if the name is meaningless? Brand X is like the Missouri mule. He has no pride of ancestry and no hope of posterity, and can only assure his next bucket of oats by pulling the load.

I have never found it easy to advocate extension of governmental regulation of the life of man, whether in the conduct of his business with the public or his purely personal affairs. Certainly, though, here is a field of law and governmental administration vital to the welfare of the nation, and from time to time modernizing changes must be made. First we must look, however, to the administration of current laws and determine to what extent necessary goals can be achieved within them.

We have talked much in America about our government of laws and not of men but have failed to recognize that laws are not self-enforcing or self-administering. That takes people and people make mistakes, so we will always have some problems no matter how good our laws. It is common practice to start the hue and cry for a new law without looking first for other remedy.

I would not have accepted this appointment had I not firmly believed—on the basis of long years of association—that the Food and Drug Administration is sound at heart. It is an agency through which a high order of loyalty flows; loyalty to the cause—and to its members

it is a cause—to which they have been dedicated. They have made mistakes, of course, and they will make more, but few unworthy ones have been found in their midst. New conditions and new products have fallen like an avalanche upon them. They have had real difficulty in keeping abreast of their responsibilities both in technological methods and in handling the vastly increased volume of business over which naturally they have no control.

On the other hand, I would have been just as reluctant if I thought that American business was generally characterized by the few scoundrels that come to light now and then. This country is made up of good solid folks and it is a pleasure to be able to work in this kind of an assignment with some of the best from both government and business.

The road may be a little rougher at one time than another but every generation has had its problems. Ours are mostly size and speed with which we have not yet learned to cope. The old medicine show pitchman never had it so good until television came along. But this too shall pass away.

Obviously it is in the interest of the consuming public and the ethical business community alike to assist the Food and Drug Administration in rendering the vital service which the public through enactment of law in the American way has required of it.

You are going to hear very little about the Advisory Committee for the next several months. Headlines serve their purpose but this is not a headline-making job. For the most part it is drab drudgery. We have available to us the services of a highly competent management consulting firm. Among the members of the Committee are varied talents and capabilities and sources of expert advice and counsel. When we report to Secretary Ribicoff next spring I hope that it will be with a high degree of agreement; that we will be able to make objective realistic suggestions, developed in a friendly atmosphere, and presented in such form as to serve the public interest through a better understanding between business and government. To these ends I shall bend my earnest effort. **[The End]**

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